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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,315	12/27/2001	David Strand	005092.00029	1059
22910	7590	08/16/2004	EXAMINER	
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601				ALEXANDER, LYLE
ART UNIT		PAPER NUMBER		
		1743		

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,315	STRAND ET AL.	
	Examiner	Art Unit	
	Lyle A Alexander	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 May 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-35 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 12454213 12/15/03
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6,8-19 and 27-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/60397 or Wilding et al. (USP 5,928,880).

WO 99/60397 teaches a microfluidic device having a flow channel(20) and a plurality of capture regions. The abstract teaches an operative unit for analysis using optical, electrical, pressure sensitive or flow sensitive detection.

Page 11 figures 6-7 are described as having 7 sheets, which have been read on

the claimed multilayer substrate. Pumps(P11-P15) control the sample flow through the device. Page 18 lines 4+ teach the materials of construction can withstand pressures of up to 600,000 psi, which have been read on the claimed excess of 100psi and 1000 psi. Page 14 teaches analysis region(304) that facilitates light absorption and photo detection of the analytes.

Claims 1-6,8-12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Dubrow et al.

Dubrow et al. teach a microfluidic device for the characterization of a polypeptide. Columns 15-16 teach operative components that include electrodes to create an electric field to drive the fluid, electrochemical detectors, PMT's and a processor for overall control of the system.

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wilding et al.

Wilding et al. teach a mesoscale sample preparation device incorporated into binding assays, polynucleotide determination/amplification and other analytical systems. Column 11 line 66 through column 12 teach describe figure 6B as teaches an analytical system comprising an analytical device(110) stacked upon a sample preparation device(10) in an appliance(70). A sample is supplied to inlet(74) where a pump(75) moves the sample to device(10) to device(110) through an interconnecting channel. Further heating and cooling elements(95) are taught. Column 13 lines 16+ teach attachment to the appliance by convention means and the "appropriate dimensioning of the devices" which has been read on the claimed alignment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/60397, Wilding et al., or Dubrow et al. in view of Mastrangelo et al.

See WO 99/60397, Wilding et al. and Dubrow et al. *supra*.

These references are silent to the claimed thermal actuator. Mastrangelo et al. teach in column 1 lines 26+ thermal actuators are known in the art as a means to convert electrical energy to mechanical energy and are well adapted to serve as pumps because of their large mechanical advantage.

It would have been within the skill of the art to modify WO 99/60397 or Dubrow et al. in view of Mastrangelo et al. and use a thermal actuator to gain the above advantages.

Claims 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/60397, Wilding et al. or Dubrow et al.

See WO 99/60397 and Dubrow et al. *supra*.

These references are silent to the claimed PEEK polymer.

The court decided In re Leshin (125 USPQ 416) the selection of a known plastic on the basis of its suitability of intended use is entirely obvious. PEEK is known to be inert, inexpensive and easy to work. It would have been within the skill of the art to modify WO 99/60397, Wilding et al. or Dubrow et al. and use a PEEK polymer to gain the above advantages as selection of a plastic based on its suitability of intended use.

Claims 15-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al.

See Wilding et al. *supra*.

Wilding et al. are silent to the claimed pressures.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable effects. The pressure chosen in a system is a result effective variable having the expected effect of increasing the reaction rate or speed of the reactions

It would have been within the skill of the art to modify Wilding et al. and use a pressure in excess of 100 psi as optimization of a result effective variable to achieve the well known and expected results of varying the speed and/or rate of the reaction.

Claims 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al.

See Wilding et al. *supra*.

Wilding et al. teach attachment of the layers, but are silent to the claimed welding.

It is notoriously well known in the art, as evidenced by the citations of Bentley et al. and WO 00/20157 in the 12/15/03 PTOL-1449, that welding of polymer layers is well known in the art. Welding is advantageous because the heat energy can be focused very precisely on the area to be attached and does not require additional adhesives that may possibly interfere with the reactants. It would have been within the skill of the art to further modify Wilding et al. and use well known welding techniques to attach the layers to gain the above advantages.

Response to Arguments

Applicant's arguments filed 5/20/04 have been fully considered but they are not persuasive.

Applicants state the '397 references fails to teach a " microfluidic substrate assembly having at least one operative component mounted aboard a multilayer laminated substrate ... " . Applicants acknowledge '397 teachings of figure 1 and the corresponding discussion on pages 14-15 of the multilayer construction.

Applicant's state '397 fails to expressly teach the taught components are "mounted aboard a multi-layer laminated substrate... " . The Office does not agree because '397 consistently describe the device as a cartridge that would meet the claimed requirement that the taught structures are mounted aboard a substrate. Applicant's further state '397 fails to teach fluid communication between the multiple layers. "397 teaches on page 4 lines 25+ "the flow elements can include fluid channels within the plane of the sheet, via (holes) to route the fluid to the next layer, analysis regions, pump interfaces and valve interfaces" which has been read on fluid communication between the multiple layers. Applicants traverse the rejection of claim 27 on the basis '397 does not teach "selectively welding" the layers together. Claim 27 is directed to a microfluidic assembly and not a method of making. Additionally, "selectively welding" is sufficiently broad as to read on just about any method of sealing. The Office has considered selectively welding as the layers are joined in a fluid tight arrangement that is met by '397. Finally, Applicants remarks concerning claims 31-35 state '397 does not teach a process of aligning the surfaces and

performing a heat weld or attachment of the layers at a predetermined place. It is inherent when making the device of '397 the layers would be aligned in the desired orientation and the weld or attachment made at specific regions along to the edge so as to not interfere with the assay.

Applicants traverse the rejection over Dubrow et al. on the basis the taught device is not disclosed as being operatively mounted aboard any device. Dubrow et al. teach on page 15 lines 26+ the taught devices are used with overall analytical systems. One having ordinary skill in the art would read this as meaning the disclosed devices are operatively mounted in an overall analytical system (e.g. if it were not mounted in the system, how would it work ?). Applicant's remarks concerning claims 13-35 under 35 USC 102(e) were convincing.

Applicants traverse the 35 USC 103 rejection of claim 7 over '397 or Dubrow et al. in view of Mastrangelo et al. Applicants state there is no motivation to make this combination. The Office disagrees and notes the rejection of record state "thermal actuators are known in the art as a means to convert electrical energy to mechanical energy and are well adapted to serve as pumps because of their large mechanical advantage". This is the motivation to make the combination.

Applicants traverse the 35 USC 103 rejection of claims 20-26 over '397 or Dubrow et al. Applicants argue the primary references do not teach PEEK and does not discuss why the obviousness rejection of record is untenable. The Office maintains the rejection is proper.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/15/03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander
Primary Examiner
Art Unit 1743
